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24504	7590	12/08/2003	EXAMINER	
THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,961

Applicant(s)

FLICK, A. BART

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-18 is/are allowed.
- 6) ☒ Claim(s) 1,3-14, 19 and 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

The amendment filed on 9/12/03 has been received and made of record in the application file wrapper. Claims 1 and 19 have been amended. Claims 22-33 have been newly added.

Claim Objections

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. More specifically, the claim depends from itself.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 24, the recitation that the shift in lateral electrical potential is deeper into the wound is unclear. The examiner would like to know, deeper than what?

As regards claim 33, the claim is indefinite in that the examiner is unable to ascertain the metes and bounds of the claim since it depends from itself.

The applicant should note the where the metes and bounds of a claim are indefinite, it is improper to base a rejection on speculation as to the meaning of the claim. *In re Steele*, 305 F.2d 858, 134 USPQ 292 (CCPA 1962). Specifically, unclear claims are indefinite, not obvious. *In re Wilson*, 424 F.2d 1382, 185 USPQ 494 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 13 and 14 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,520,664 ("Bricault, Jr. et al.").

As regards claims 1 and 4, Bricault, Jr. et al. disclose polymeric implants (col. 4, lines 64 and 65) having antimicrobial coatings, such as, gold, silver, platinum, etc. As regards applicant's recitation of no galvanic cell action, note col. 5, lines 48-64.

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The applicant should note that silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs (Note exhibit A). Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

Moreover, the applicant should note the device of Bricault, Jr. et al. is capable of producing a lateral shift in the electrical potential of a pathology.

Bricault, Jr. et al. fail to explicitly teach that the resistance of the metals is less than 1000 ohms/cm. However, since the applicant discloses some of the same conductive materials as those disclosed by Bricault, Jr. et al., (e.g., silver and gold), it is inherent that the same metals have the same resistance. Note applicant's admitted disclosed resistances on page 32-33 of the specification.

As regards claims 13 and 14, Bricault, Jr. et al. disclose a tubular shaped catheter (Figs. 5 and 6a), which is capable of draining a wound or body cavity (thereby being a wound drain).

Claims 1, 4, 19, 23, 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,004,667 ("Sakurada et al.").

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As regards claims 1 and 4, Sakurada et al., disclose a bandage or wound dressing comprising a fibrous substrate coated with silver or nickel, which inherently has a resistance of 1000 ohm/cm or less, according to applicant's own admission (see the specification).

Sakurada et al. also disclose that **the metallic ions may be distributed into the body without galvanic cell action** (col. 5, line 43-48, col. 6, lines 32-39 and col. 12, line 21- col. 13, line 22)

As regards altering the electrodynamic process of a portion of the body, silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

Moreover, the applicant should note the device of Sakurada et al. is capable of producing a lateral shift in the electrical potential of a pathology.

As regards claims 19, 23, 28, 29 and 32, Sakurada et al. disclose a medical device (bandage) for treating a portion of the body, comprising at least one layer of a conductive material (201) coated with silver or nickel, having an inherent resistance of

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less than 1000 ohms/cm (see the specification). At col. 12, Sakurada et al. disclose that a dual layer of conductive material may be used.

Sakurada et al. further disclose that the conductive layer inherently comprises a biologically inert polymer since it is used on the human body, wherein no galvanic cell action or external energy source is required to alter an electrodynamic process or electric parameters of the portion of the body.

The applicant should note that steps (b) and (c) inherently occur when the metallic ions from the substrate enter the body.

As regards claims 25 and 26, silver is known to produce an analgesic effect, therefore the migration of the metallic silver ions into the body is capable of producing an analgesic effect. Additionally, silver is an antimicrobial agent which helps to heal wounds faster.

As regards claim 27, note col. 12, lines 44-46, which discloses that a moisture vapor impermeable film may be provided over the polymer to prevent evaporation of the fluid.

As regards claim 30, the substrate is coated with conductive material, therefore the surface of the substrate has the conductivity of the conductive material, which has an inherent resistance of less than 1000 ohms/cm (see the specification).

As regards claim 32, Sakurada et al. disclose at col. 12, 58-59 may include a dual layer of conductive material.

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Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,615,705 ("Scales et al.").

As regards claim 6, Scales et al. disclose antimicrobial implants (e.g., orthopaedic plates, pins and artificial joints) comprising at least one layer of conductive material (metallic silver). Applicant admits in the specification that silver has a resistance of less than 1000 ohm/cm. Scales et al. further disclose that the layer of conductive material is coated on an implant constructed from a bioinert material (e.g., a non-toxic synthetic plastics material (polymer).

The applicant should note that it is inherent in the disclosure that no external energy or galvanic cell action is required to alter an electrodynamic process of a portion of the body since the application of silver ions to the body inherently performs the function of altering the electrodynamic process of a portion of the body to which it is applied .

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

Moreover, the applicant should note the device of Sakudura et al. is capable of producing a lateral shift in the electrical potential of a pathology.

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The examiner concedes that at col. 3, lines 68-col. 4, line 3, Scales et al. mentions that in order to promote galvanic action producing silver ions, specific silver alloys may be used. However, the applicant is directed to col. 4, lines 49-52, wherein it is disclosed that silver ions are produced using metallic silver and col. 5, lines 24-31, wherein it is disclosed that silver ions are produced using bioerosion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scales et al.

As regards claim 7, Scales et al. fail to teach the medical appliance a dental appliance. However, the examiner contends that the technology used to the apply

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metal coatings to the pins and plates of the disclosed endoprosthetic implants of Scales et al., can also be used to coat dental appliances.

Furthermore, the examiner contends that dental implants are a form of an endoprosthetic implant. And, one having ordinary skill in the art would have been motivated to place an antimicrobial coating on any implant, including a dental implant (appliance) for the purpose of preventing antimicrobial growth thereon.

Claims 3, 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.s. Patent No. 6,004,667 ("Sakurada et al.").

As regards claim 3, Sakurada et al. fail to teach the substrate is constructed from polyester and acrylic fibers or a gauze. However, since gauze is conventionally constructed material, such as, for example, cotton, one having ordinary skill in the art would have found it obvious to select cotton gauze because it is breathable.

Additionally, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

As regards claims 5 and 8-12, Sakurada et al. fail to teach the bandage is shaped for use around external fixture pin structures, shaped for use around ostomy sites, shaped for use around tracheostomy sites, shaped for use around catheter sites, and shaped for packing body cavities. However, it has been held that the shape of a prior art device is a design consideration within the level of ordinary skill in the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). As such, one having ordinary skill in

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the art would have found it obvious to change the shape of the bandage to fit the portion of the body for which the device is intended.

Response to Arguments

Applicant's arguments filed 9/12/03 have been fully considered but they are not persuasive. More specifically, applicant's arguments that the devices of Bricault, Jr, et al., Sakurada et al. and Scales do not teach or suggest device which alter the electrical potential when positioned to conductively bridge healthy surfaces surrounding the pathology. The examiner contends that although, Bricault, Jr, et al., Sakurada et al. and Scales do not teach altering the electrical potential when positioned to conductively bridge healthy surfaces surrounding the pathology, the devices when positioned on a user is capable of performing such a function.

In response to applicant's arguments that Bricault, Jr, et al., Sakurada et al. and Scales do not mention electrical potential, it is conventionally known in the art that wound fluid is an electrolytic fluid and has electrical potential. Furthermore, the metal ions of the devices of Bricault, Jr, et al., Sakurada et al. and Scales react with the electrolytic wound fluid in order to accomplish their disclosed goals. When, the electrical potential of the wound fluid is altered, the analgesic and antimicrobial effects arrive.

Allowable Subject Matter

Claim 15-18 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
November 17, 2003